UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA

Plaintiff,

v.

ZIMMER, INC., and ZIMMER
HOLDINGS, INC., Delaware
Corporations; JAMES LEE
SORENSON, and SDI RESIDUAL
ASSETS LLC as successors in interest
to SORENSON DEVELOPMENT,
INC., a Utah Corporation, nka SDI
LIQUIDATING CORPORATION;
SORENSON MEDICAL PRODUCTS
INC., a Utah Corporation; as successors
in interest to SORENSON MEDICAL,
INC., a Utah Corporation, nka SMI
LIQUIDATING INC.;

Case No.:	

Personal Injury; Negligence; Products Liability (28 U.S.C.§1332)

> Related to: CV-08-0399, et al., Actions Consolidated before Judge John R. Tunheim and Magistrate Judge Jeffrey J. Keyes

COMPLAINT

DEMAND FOR JURY TRIAL

Defendants.

NATURE OF THE CASE

1. Plaintiff Kenneth R. Almberg developed chondrolysis in his shoulder after being implanted with a pain pump following shoulder surgery. The pain pump was designed and marketed for intra-articular continuous administration of anesthetic drugs. As a result, the plaintiff has suffered the complete or nearly complete loss of cartilage in the shoulder joint, an injury that is irreversible, disabling, and extremely painful. This lawsuit asserts claims for negligence, strict product liability for design defect, and strict product liability for failure to warn against defendants.

JURISDICTION, VENUE AND PARTIES

- 2. Venue is proper in this district under 28 U.S.C. §1391 because all defendants transact business in this district.
- 3. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy exceeds Seventy-Five Thousand Dollars (\$75,000.00), exclusive of interest and costs, and because there is complete diversity of citizenship between the Plaintiff and Defendants.

The Plaintiff

- 4. Kenneth R. Almberg was at all relevant times a resident and citizen of Oregon.
- 5. Plaintiff Kenneth R. Almberg underwent shoulder surgery near Portland, Oregon. Based on information and belief, a "pain pump" designed and manufactured by the Sorenson defendants and distributed and marketed by the Zimmer defendants was implanted into his shoulder on April 15, 2002 by his orthopedic surgeon. Following plaintiff's surgery, plaintiff was administered 270/300cc 0.5% Sensorcaine with epinephrine in the Zimmer/Sorenson pain pump. The pain pump used following Mr. Almberg's surgery injected pain relief medication directly into his shoulder joint on a continuous basis, for up to 72 hours or more following his surgery. Plaintiff was diagnosed with degenerative joint disease on or around October 24, 2003.
- 6. The incidents causing the injury, and from which the plaintiff's claims arise, occurred on or shortly after the administration of anesthetics via the

Zimmer/Sorenson post-operative pain pump following his surgery on April 15, 2002. Plaintiff first learned that he could file a claim for his chondrolysis caused by the administration of pain medication from a pain pump directly to the shoulder joint shortly before the filing of this complaint.

The Defendants

- 7. Defendants Zimmer Inc. and Zimmer Holdings, Inc. are Delaware corporations with their principal places of business in Warsaw, Indiana. The defendants conducted regular and sustained business in Minnesota by rebranding, marketing and distributing the pain pumps in Minnesota. Plaintiff collectively refers to these companies as the "Zimmer defendants."
- 8. Defendant Sorenson Medical Inc., is a Utah Corporation with its principal place of business in Utah. On information and belief, the assets, including business goodwill of Sorenson Medical Inc. were transferred to defendant Sorenson Medical Products Inc., a Utah corporation controlled by the same family as Sorenson Medical Inc. On information and belief, the assets, including business goodwill of Sorenson Medical Inc. were transferred to Sorenson Development Inc. as a purported creditor of the business. On information and belief, when Sorenson Medical remained as a corporate shell without assets, it changed its name to SMI Liquidating, Inc. Sorenson Development Inc., is a Utah Corporation controlled by the same family as Sorenson Medical Inc. and Sorenson Medical Products Inc. On information and belief, the assets transferred from Sorenson Medical to Sorenson Development were again transferred from Sorenson

Development to James Lee Sorenson, the person who controls the Sorenson family businesses identified as defendants herein. On information and belief, when Sorenson Development Inc. remained as a corporate shell without assets, it changed its name to SDI Liquidating Corporation. In the meantime, the name and business goodwill of "Sorenson Development" was used by Sorenson Residual Assets LLC, a company purportedly formed by Sorenson Development Inc., without accounting for Sorenson Development Inc.'s nonexistence as a Utah Corporation. Plaintiffs refer to each defendant named in this paragraph collectively as "Sorenson defendants."

- 9. To the extent that Sorenson Medical is an unfunded corporate shell and not sufficiently capitalized to answer for its responsibilities, the other defendants are answerable as successors in interest to its liabilities. To the extent that Sorenson Medical avoids its responsibility for the damage it has done to Plaintiff, and has insufficient funds to pay plaintiff's damages, the remaining Sorenson defendants are liable for one or more of the following reasons:
 - A. These transactions amount to a mere consolidation or merger with Sorenson Medical Inc. and Sorenson Development, Incorporated;
 - B. The successors to Sorenson Medical are mere continuations of Sorenson Medical;
 - C. The transfer of assets among the Sorenson Companies was entered fraudulently to escape liability for debts;
 - D. There was insufficient consideration for the transfer of assets from Sorenson Medical Incorporated and from Sorenson Development, Incorporated;

- E. There was no legitimate business purpose to these series of transactions and deceptive acts other than to hinder, delay, and defraud creditors;
- F. All companies conduct their business as a single business, designated "Sorenson Companies" and located at 2511 S. West Temple, Salt Lake City, UT 84115;
- G. The Sorenson defendants currently use the names/trademark "Sorenson Medical" and "Sorenson Development, Incorporated," without accounting for their supposed nonexistence as Utah Business entities;
- H. Plaintiffs reserve the right to add new allegations and new Sorenson defendants if the Sorenson companies continue to transfer assets in an attempt to escape liability.
- 10. The Sorenson defendants conducted regular and sustained business in Minnesota by selling and distributing their products in Minnesota.

FACTS COMMON TO ALL CLAIMS

- 11. At all relevant times, the defendants designed, manufactured, and distributed a product called a "pain pump," a medical device intended to deliver, via catheter, continuous doses of pain relief medication directly into the shoulder joint space. The pain pumps deliver anesthetic pain medication directly into the operative site for 72 hours or more immediately following shoulder surgery.
- 12. The pain pumps are designed and intended to be used with commonly used anesthetics such as lidocaine or marcaine, with or without epinephrine, in volumes of 250 cc's or more, over two days or more. The continuous injection of such medications at such doses over time directly into the shoulder joint, however, can cause serious and

permanent damage to the cartilage of the shoulder joint. Plaintiff Kenneth R. Almberg had a pain pump inserted post-operatively, and he received dangerous doses of continuously injected medication in his shoulder joint. As a result, he suffered narrowing of the joint space and/or a condition called "chondrolysis," which is the complete or nearly complete loss of cartilage in the shoulder joint, an irreversible, disabling, and extremely painful condition.

- 13. Plaintiff has suffered severe damage, and is likely to undergo a complete shoulder joint replacement as a result of the narrowing of the joint space and/or chondrolysis caused by the dangerously defective pain pump. Plaintiff is likely to undergo additional shoulder joint replacement surgeries throughout the rest of his life.
- 14. None of the defendants warned plaintiff Kenneth R. Almberg or his surgeon about the unreasonable risks and dangers of using the pain pumps and anesthetic medications in this manner. Plaintiff's surgeon used the pain pump in the manner instructed and directed by defendants.

FIRST CLAIM FOR RELIEF

(Strict Products Liability: Design Defect, Failure to Warn)

- 15. Plaintiffs reallege all previous paragraphs.
- 16. The pain pump device, and the anesthetic medications used in it, was unreasonably and dangerously defective beyond the extent contemplated by ordinary patients with ordinary knowledge regarding the device, in one or more of the following particulars:

- A. The labeling failed to instruct or warn the U.S. medical community that the safety of the device and its medications had not been established for use in the shoulder joint space;
- B. The labeling failed to disclose to the U.S. medical community that continuous injection of commonly used anesthetics such as Sensorcaine (bupivacaine), with or without epinephrine, in volumes of at least 250 cc's, for two or more days, into the shoulder joint space, may cause serious and permanent injury to the joint cartilage;
- C. The labeling failed to include a precaution against placing the catheter of the pain pump in the shoulder joint space;
- D. The labeling failed to provide to the U.S. medical community adequate instructions for the safe use of the device, failing specifically to identify anesthetic medications that could be safely and effectively used in the shoulder joint space;
- E. The labeling failed to disclose to the U.S. medical community that the effectiveness of the device was uncertain for use in the shoulder joint space;
- F. The labeling failed to disclose to the U.S. medical community that the FDA had considered the defendants' request to put this indication in the pain pump label, and then had rejected this precise indication for the pain pumps' use, to deliver the pain medicine directly into the joint space.
- G. The products were designed to inject commonly used medications associated with damage to articular cartilage directly into the shoulder joint; and
- H. When used as designed, the pain pumps delivered, over time, dangerously high doses of medication directly into shoulder tissue.

- 17. The product defects alleged above were substantial contributing causes of the injuries suffered by these plaintiffs. Specifically, the pain pumps and the anesthetic medication used in them caused plaintiff Kenneth R. Almberg to suffer the permanent loss of cartilage in his shoulder, resulting in severe pain and discomfort of the shoulder, loss of use and function of the shoulder and arm, and requiring multiple surgeries. The use of the pain pumps and the anesthetic medication used in them also rendered the therapeutic benefits of the shoulder surgery worthless.
- 18. Plaintiff Kenneth R. Almberg will likely require future medical care, as he ages, related to his chondrolysis, including a likely future joint replacement. In addition, he has suffered mental distress and anguish and has suffered permanent impairment of the use and function of his affected upper extremities.
- 19. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff has sustained and will continue to sustain severe physical injuries, emotional distress, mental anguish, economic loss and other damages for which Plaintiff is entitled to compensatory and other damages and relief in an amount to be proven at trial.

SECOND CLAIM FOR RELIEF

(Negligence)

- 20. Plaintiff realleges all previous paragraphs.
- 21. At all relevant times, each of the defendants knew or reasonably should have known that their pain pumps and the anesthetic medication used in them were unreasonably dangerous and defective when used as directed and as designed. A

reasonably careful search and review of the scientific and medical literature, and other information, should have indicated to the defendants that:

- A. Commonly used anesthetics likely to be used in their pain pumps, such as lidocaine and bupivacaine, with or without epinephrine, were harmful to human and animal articular cartilage;
- B. Use of the pain pumps in a joint space had not been approved by the F.D.A., and in fact had been specifically rejected by the F.D.A.;
- C. Continuous injection of 250 cc's or more of such medications, through a catheter, directly into the shoulder joint, for two days or more, had not been adequately tested for safety or effectiveness;
- D. The risk of chondrolysis and other serious post-operative problems associated with using the pain pumps and their medications as designed and instructed outweighed the possible benefits of such use.
- 22. Based on what they knew or reasonably should have known as described above, defendants were negligent in one or more of the following particulars:
 - A. In failing to instruct or warn the U.S. medical community that the safety of the device had not been established for use in the shoulder joint space;
 - B. In failing to disclose to the U.S. medical community that continuous injection of commonly used anesthetics such as lidocaine or marcaine, with or without epinephrine, in volumes of at least 250 cc's, for two or more days, into the shoulder joint space, may cause serious and permanent injury to the joint cartilage;
 - C. In failing to include a precaution against placing the catheter of the pain pump in the shoulder joint space;

- D. In failing to provide to the U.S. medical community adequate instructions for the safe use of the device, specifically failing to identify anesthetic medications that could be safely and effectively used in the shoulder joint space;
- E. In failing to disclose to the U.S. medical community that the effectiveness of the device with these medications was uncertain for use in the shoulder joint space;
- F. Manufacturing a product designed to directly inject into the shoulder joint commonly used medications associated with damage to articular cartilage;
- G. Manufacturing a product designed to deliver, over time, dangerously high doses of medication directly into shoulder tissue;
- H. Failing to conduct studies or otherwise investigate the potential harm to articular cartilage when exposed to the pain pumps and anesthetic medications in volumes of at least 250 cc's, for two or more days, into the shoulder joint space; and
- I. Promoting the pain pumps for use in the joint space after the FDA had considered and rejected such an indication.
- 23. The negligent acts and omissions alleged above were substantial contributing causes of the injuries suffered by the plaintiff. Specifically, the pain pumps caused plaintiff Kenneth R. Almberg to suffer the permanent loss of cartilage in his shoulder, resulting in severe pain and discomfort of his shoulder, and loss of use and function of his shoulder and arm. The use of the pain pumps also rendered the therapeutic benefits of his shoulder surgery worthless. As a result of defendants' negligent acts and omissions, plaintiff Kenneth R. Almberg is will incur additional

medical expenses as he ages related to his chondrolysis, including a likely future joint replacement. In addition, plaintiff has suffered mental distress and anguish and has suffered permanent impairment of the use and function of his affected upper extremities.

- 24. The injuries suffered by plaintiff were the reasonably foreseeable results of defendants' negligence.
- 25. As a direct and proximate result of Defendants' wrongful conduct, plaintiff has sustained and will continue to sustain severe physical injuries, emotional distress, mental anguish, economic loss and other damages for which plaintiff is entitled to compensatory and other damages and relief in an amount to be proven at trial.

PRAYER FOR RELIEF

WHEREFORE, plaintiff demands judgment against each of the defendants as follows:

- a. On the First and Second Claims for Relief, plaintiff Kenneth R. Almberg prays for judgment against each defendant for economic and noneconomic damages exceeding \$75,000 in amounts to be proven at trial;
- b. Plaintiff seeks his reasonable costs and disbursements incurred herein, including the attorney fees he incurs in prosecuting this action; and
 - c. Plaintiff prays for such other and further relief as justice requires.

JURY DEMAND

Plaintiff requests trial by jury.

Dated: April 12, 2010

LOCKRIDGE GRINDAL NAUEN P.L.L.P.

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